IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE: ABDEL-MONEM, et al.	
	APPEAL NO. _____
SERIAL NO: 10/706,900	
FOR: METAL COMPLEXES OF ALPHA AMINO DICARBOXYLIC ACIDS	
	BRIEF ON APPEAL
FILED: November 13, 2003	
GROUP ART UNIT: 1625	

To the Commissioner of Patents and Trademarks
Mail Stop PATENT APPEAL,
P. O. Box 1450,
Alexandria, VA 22313-1450

Dear Sirs:

Please enter the following Brief on Appeal into the record.

CERTIFICATE OF MAILING BY EXPRESS MAIL

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I. INTRODUCTION

This is an appeal of the Final Rejection dated January 12, 2005, finally rejecting claim 1. The appealed claim is set forth in an attached Appendix.

II. REAL PARTY OF INTEREST

The real party of interest in the present appeal is Zinpro Corporation, a Minnesota corporation of Eden Prairie, Minnesota, assignee by assignment from the co-inventors recorded in the parent application of which this is a divisional, U. S. Patent Application Serial No. 10/272,382 recorded on February 24, 2003 at Reel/Frame 013778/0042.

III. RELATED APPEALS AND INTERFERENCES

There is a related appeal at the time of this filing of yet another Divisional case U. S. Serial No. 10/712,422. It is also expected that the parent case relating to the compounds and compositions, as opposed to this method of making case, (parent case Serial No. 10/272,382 filed 10/16/2002) may also be pending on appeal at the same time as this case, unless prosecution is resolved short of appeal.

IV. STATUS OF CLAIMS

Claim 1 was originally submitted as claim 14 in the parent application, U. S. Serial No. 10/272,382, but was divided out in a response to a restriction requirement in the parent application. This Divisional of U. S. Serial No. 10/272,382 was filed November 13, 2003 in response to a restriction requirement, and was assigned Serial No. 10/706,900. Claim 1 was amended October 21, 2004 in response to an August 6, 2004 Office Action. Final rejection

of amended claim 1 was issued January 12, 2005. An Amendment After Final Rejection followed by a Supplemental Amendment After Final Rejection was filed March 1, 2005. It was entered with an Advisory Action of March 23, 2005.

Following the Final Rejection of January 12, 2005 and the Advisory Action of March 23, 2005, Appellant filed a Notice of Appeal dated March 31, 2005. The claim appealed is claim 1.

V. STATUS OF AMENDMENTS

An Amendment After Final Rejection was filed February 15, 2005, and a Supplemental Amendment After Final Rejection was filed March 1, 2005, which was entered on March 23, 2005. A Notice of Appeal was timely filed on March 31, 2005.

VI. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 sets forth a method making 1:1 neutral complexes of an essential trace element and a dicarboxylic alpha amino acid. The process assures high yield, little or no hydroxide precipitation and highly processable small crystals of pure product.

VII. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claim 1 stands rejected as obvious over Cardinal, U. S. Patent No. 2,849,468. All other previously urged grounds of objection have been withdrawn.

VIII. ARGUMENT

A. Claim 1 is Not Obvious Under 35 U.S.C. § 103(a) over Cardinal, U. S. Patent No. 2,849,468 for Three Reasons

1. Claim 1 Prepares Precise Compounds of Different Structure Than the Cardinal Reference

It is important to remember that claim 1 indicates directly in its language that it is preparing precise compounds, i.e., 1:1 neutral complexes of essential trace elements, such as for example zinc, and dicarboxylic α-amino acids, such as for example glutamic acid. This is accomplished by mixing a water soluble monobasic and amino dicarboxylic acid with a water soluble metal salt of the trace element in salt form and adjusting the pH to neutral in a manner that avoids formation of insoluble metal hydroxides. This involves pH adjustment preferably with slow addition and stirring to avoid high pH spikes (see Specification, p. 9, lines 3-30 and p. 10, lines 1-25).

Claim 1 was rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal, U.S. Pat. No. 2,849,468 on the basis that if a skilled artisan in the art had desired to produce a 1:1 neutral complex of zinc and glutamic acid different from the 1:1.5 complex shown in Cardinal Example III, such artisan would have been motivated to produce such a complex selectively as an alternative by using the teachings of the Cardinal reference because "glutamic acid in the form of its sodium salt is in demand for the purpose of flavor enhancement" (col. 1, line 20). The Examiner further argues that the skilled artisan would expect the formation of the 1:1 neutral complex of zinc and glutamic acid to be successful from the guidance (see col. 4, lines 4-7) shown in the prior art. Applicants have from the

beginning urged neither this reference nor the flowed logic of the rejection supports *prima facie* obviousness.

The Examiner's assertion that Cardinal provides guidance to produce Applicants' 1:1 (*emphasis added*) neutral complexes appears to be based on an incorrect interpretation of Cardinal. The purpose of Cardinal is to precipitate the maximum amount of glutamic acid from its solution and to prepare some unknown zinc salts of glutamic acid. (See e.g. Col. 2, lines 43-45). In fact, Cardinal states that, "[t]he exact chemical formula for these zinc glutamate salts prepared in accordance with the instance process is not definitely known." (Col. 4, lines 17-19). It is not understood how it would have been obvious to have prepared Applicants' 1:1 neutral complexes, which the Examiner admits are novel, based on the teachings of a reference that was admittedly unaware of what in fact it was making. (col. 4, lines 17-19).

Further, contrary to the Examiner's assertion, Cardinal does not disclose that his salt has 1-2 moles of zinc per mole of glutamic acid. Upon careful reading of the reference, persons skilled in the art would readily appreciate that Cardinal is instead stating that 1-2 molar equivalent of a zinc salt was added in order to precipitate the glutamic acid (Col. 3 lines 71-75 to Col. 4 lines 1-7). In this regard, Cardinal notes that while between 1 and 2 molar equivalents of zinc were required to precipitate pure glutamic acid from solution, 8-10 molar equivalents of zinc were required to precipitate the same glutamic acid from, "Steffen's filtrate hydrolyzate end liquors containing generally between 1.5% and about 2.5% glutamic acid concentration." (Col. 3 line 75 to Col. 4 lines 1-7). This focus on maximizing the

precipitation of glutamic acid by adding excess of one reactant to drive or shift the reaction towards another is demonstrated throughout the specification and examples (see e.g. Example II, "The zinc magnesium glutamate product weighed about 46.9 grams, and precipitation was about 98.8% complete.") (col. 4, lines 55-58).

In contrast, the purpose of the present invention is to provide neutral 1:1 complexes of trace elements having commercial utility for nutritional supplementation that are superior to currently available products used for the same purpose. This required the identification of desirable chemical, physical and nutritional properties, all in a single species. Based on these requirements, the present inventors designed and prepared potential complexes, determined their physical and chemical properties, and selected those complexes that possessed the desired properties, i.e. enhanced bioavailability while also having good processability. Complexes demonstrating superior bioavailability in animal studies were further evaluated for improving the performance of livestock. (See Spec. pp. 7-8). Cardinal does not teach the process of claim 1. His mole ratios are wrong, his process does not include steps shown in claim 1 and he admits he does not know what he gets!

In summary, it cannot be seen how Cardinal can create a *prima facie* case of obviousness of the methodology of claim 1 since he does not teach the steps of claim 1 nor the preparation of the same compounds, and instead acknowledges "the exact chemical formula for these zinc glutamate salts prepared in accordance with the instant process is not definitely known" (col. 4, lines 17-19). The vague term "zinc glutamate" could refer to three distinct different moieties, only one of which would be a 1:1 neutral complex. It is simply

guesswork as to which. Such a vague and ambiguous reference cannot make obvious the process of claim 1.

2. The pH Adjustment to Neutral to Avoid Insoluble Metal Hydroxides is Not Taught by Cardinal

The limitation referred to in this heading is expressly a claim limitation of claim 1. Nothing in Cardinal shows this limitation. It is silent on this point. Instead, for example, Cardinal in example I "freshly precipitates zinc hydroxide" (col. 4, line 34); example II uses a slightly acid pH (6.7); and example III, slightly (basic 7.3). In fact, example III shows a variety of non-neutral pH's (Table I). But, nothing is mentioned in the description of the claim limits of the invention; Cardinal is a process of precipitating out glutamic acid, as something of unknown structure they call zinc glutamate.

3. Quick Cooling for Formation of Small Crystals is Not Taught

Quick cooling is also a claim limit. 1:1, neutral zinc glutamate small crystals formed by quick cooling are simply not taught by the reference either. Example I of Cardinal stands for 10 hours (4/38; Example II doesn't say how it was cooled; Examples II, IV and V say nothing on the subject). Thus, Cardinal prepares something at best indefinite, using a different mole ratio than that used for 1:1 neutral complexes, and prepares glutamic acid salts with the purpose of precipitating glutamic acid not for nutritional supplementation. Since the reference teaches different ratios, i.e., not 1:1 but 1:1.5, teaches no structure whatsoever and does not teach the methodology described in claim 1, it cannot be seen how it makes a *prima facie* case of obviousness for the process.

B. Rebutting the Examiner's Arguments

The Examiner argues against Applicant's position that Cardinal does not appreciate the difference between 1:1 and other ratio complexes by saying Cardinal teaches a range from 1 mole to 2 moles (col. 4, line 5-7). While this may be true, it is guess work as to what in fact he gets which is the point. A careful reading of the language (col. 4, lines 5-7) indicates that "when the same salt is prepared from refined glutamic acid, between (*emphasis added*) about 1 mole and about 2 moles of zinc are employed per mole of glutamic acid." This contemplates more than 1 mole per mole of glutamic acid which must be something different than 1:1 complexes. Careful reading, therefore, shows that the reference teaches away from 1:1 neutral complexes. Zinc has a positive +2 charge in its ionic form. Glutamic acid is 2-amino pentane dioic acid and it has the possibility of having one carboxyl (COO-) negative moiety or two carboxyl (COO-) negative moieties, since it is a dicarboxylic acid. Three separate possible compounds are therefore referenced by zinc glutamate, a 1:1 neutral complex where one zinc ion moiety associated with one glutamate moiety with each of the dicarboxylic acids having its associated proton removed; a 1:2 complex for one zinc ion associated with two glutamate moieties with each having only one proton removed; and a compound where the zinc complex is the cation and has a single positive charge and is associated with one glutamate moiety. These may be roughly schematically represented as follows "G represents glutamate, ZnG, or $[Zn(G)]^+$, or $Zn(G)_2$." Since Cardinal leaves only wild guess work as to which is formed, and it is known specifically that it is not 1:1 as

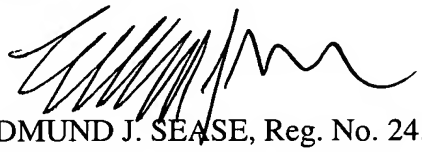
defined by the claim here, how can it make a *prima facie* obviousness case? The answer is it simply cannot.

IX. CONCLUSION

Claim 1 is non-obvious over the Cardinal reference and the Examiner should be reversed and the case allowed.

Enclosed herein please find the Appeal Brief and the required fee of $250 for a small entity. Also enclosed is a Request for Oral Hearing and the required fee of $500. If this amount is not correct, please consider this a request to debit Deposit Account No. 26-0084 accordingly.

Respectfully submitted,



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APPENDIX

Claim 1. A method of preparing 1:1 neutral complex of essential trace elements and a dicarboxylic alpha amino acid, comprising: mixing a water soluble monobasic and amino dicarboxylic acid with a water soluble metal salt of the trace element in salt form; adjusting the pH to neutral in a manner to avoid formation of insoluble metal hydroxides; and, quickly cooling the reactants to form small crystals of the neutral complexes.